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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,808	07/27/2001	Mark John Gibbs	10338-2U1 (2441651/VPA)	2166
570	7590	07/02/2004	EXAMINER	
AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103-7013			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,808	GIBBS ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 27 April 2004 in which claims 1 and 3-6 were amended and claim 34 was added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 4 December 2003 are withdrawn in view of the amendments and new grounds for rejection. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

The examiner for this application has changed. Please address future correspondence to BJ Forman, Art Unit: 1634.

Claims 1-9 and 34 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

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designated the United States and was published under Article 21(2) of such treaty in the English language.

The claims are drawn to a set of oligonucleotide probes. The claimed probes are described by their function (e.g. “a respective promiscuous probe is capable of hybridizing to a target shared between at least two of said target polynucleotides”, “wherein a predefined combination of promiscuous probes is capable of hybridizing to said at least two target sequences” and “said predefined combination providing specificity of detection”) and/or by the target (e.g. “wherein at least one target polynucleotide comprise at least two target sequences shared with one or more other target polynucleotides”). The claimed probe functions and target descriptions are recitations of intended use for the claimed probes. However, the recited uses do not define structure or composition of the probes.

The courts have stated that claims drawn to a product must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

Furthermore, the above recitations include broad terminology e.g. “respective”, “predefined” and “specificity”. The phrases “respective promiscuous probe”, “predefined combination” and “specificity of detection” are relative phrases which are interpreted broadly to encompass any probe relationship, any combination and any degree of specificity because the claims have not provided guidance for defining the claimed “respective”, “predefined” and “specificity”.

3. Claims 1-4, 6 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al (U.S. Patent No. 5,541,308, issued 30 July 1996).

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Regarding Claim 1, Hogan et al disclose a set of probes for detecting at least one target polynucleotide (e.g. *Mycobacterium avium*) from a plurality of different targets (Column 12, lines 58-Column 13, line 35). The set of probes comprises a collection of different promiscuous probes (i.e. genus-specific probes 1-4, Example 8, lines 15-53) wherein the probes are capable of hybridizing to sequences shared by at least two target sequences (i.e. *Mycobacterium* genus) wherein a predefined combination of promiscuous probes hybridizes to at least two targets and provides specificity of detection (Tables 22-23).

Regarding Claim 2, Hogan et al disclose the set further comprising a plurality of different predefined combination of probes, each providing specificity of detection (i.e. genus-specific probes 1-4, Example 8, lines 15-53 and species-specific probes for (*M Avium*, *M. intracellulare*, and *M. tuberculosis*)(Column 13, lines 2-35 and Tables 1-23).

Regarding Claim 3, Hogan et al disclose the set comprising at least one probe capable of hybridizing to a unique target(i.e. *M Avium*, *M. intracellulare*, and *M. tuberculosis*) (Column 13, lines 2-35 and Tables 1-23).

Regarding Claim 4, Hogan et al disclose the set comprising at least one probe “capable” of hybridizing to a pivot sequence. The genus specific probes of Hogan et al illustrated in Table 22, are “capable” of hybridizing to a pivot sequence as defined in the specification. The specification (§ 66) defines “pivot sequence to “refer to a target sequence that occurs in two or more of the target polynucleotides but not in all of the target polynucleotides.”

Furthermore, the recitation “capable of hybridizing to” is a recitation of intended use which does not define or describe the structure or composition of the probe. The recitation is interpreted broadly to encompass possible hybridization between any nucleotides of the probe and target.

Regarding Claim 6, Hogan et al disclose the set wherein the probes are immobilized on a solid support (i.e. magnetic bead Example 8, Column 28, lines 2-14). It is noted that the probe target complex are bound to the magnetic particles. The claim does not require the

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probe be immobilized prior to hybridization nor does the claim define the probe as being covalently/directly attached to the solid support. Hence, the claimed "immobilized" encompasses the complex immobilization of Hogan.

Regarding Claim 34, Hogan et al disclose a set of probes for detecting at least one target polynucleotide (e.g. *Mycobacterium avium*) from a plurality of different targets (Column 12, lines 58-Column 13, line 35). The set of probes comprises a collection of different promiscuous probes (i.e. genus-specific probes 1-4, Example 8, lines 15-53) wherein the probes are capable of hybridizing to sequences shared by at least two target polynucleotides each comprising two sequences (i.e. *Mycobacterium* genus) wherein a predefined combination of promiscuous probes hybridizes to at least two targets and provides specificity of detection (Tables 22-23).

4. Claims 1-4, 6-9 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998).

Regarding Claim 1, Gentalen et al disclose a set of probes for detecting at least one target polynucleotide, the set comprising a collection of different promiscuous probes capable of hybridizing to a target shared between two target polynucleotides (common probe and polymorphic site) wherein a predetermine combination of probes is capable of hybridizing to at least two target sequences providing specificity of detection (Column 2, line 51-Column , line 31; Column 8, line 45-Column 10, line 8 and Claim 8).

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Regarding Claim 2, Gentalen et al disclose the set wherein a plurality of different combinations provide specificity of detecting a different target (Column 9, line 38-Column 10, line 8).

Regarding Claim 3, Gentalen et al disclose the set comprising at least one non-promiscuous probe capable of hybridizing to a unique target i.e. polymorphism (Column 9, line 38-Column 10, line 8).

Regarding Claim 4, Gentalen et al disclose the set comprising at least one probe that is capable of hybridizing to a pivot sequence which divides the polynucleotides into groups i.e. single species target-specific control probes (Column 13, lines 21-42).

Regarding Claim 6, Gentalen et al disclose the set immobilized on a solid support (Column 17, line 23-55).

Regarding Claims 7-8, Gentalen et al disclose the set immobilized on a high-density array (Column 11, lines 11-28).

Regarding Claim 9, Gentalen et al disclose the probes linked to the support via a spacer e.g. aminotriethoxysilane (Column 17, lines 24-30) or using the methods recited at Column 11, lines 45-61).

Regarding Claim 34, Gentalen et al disclose a set of probes for detecting at least one target polynucleotide, the set comprising a collection of different promiscuous probes capable of hybridizing to a target shared between two target polynucleotides (common probe and polymorphic site) wherein a predetermined combination of probes is capable of hybridizing to at least two target polynucleotides comprise two target sequences providing specificity of detection (Column 2, line 51-Column , line 31; Column 8, line 45-Column 10, line 8 and Claim 8).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998) in view of Lockhart et al (6,329,140, issued 11 December 2001).

Regarding Claim 5, Gentalen et al disclose a set of probes for detecting at least one target polynucleotide, the set comprising a collection of different promiscuous probes capable of hybridizing to a target shared between two target polynucleotides (common probe and polymorphic site) wherein a predetermine combination of probes is capable of hybridizing to at least two target sequences providing specificity of detection (Column 2, line 51-Column , line 31; Column 8, line 45-Column 10, line 8 and Claim 8). Gentalen et al further teach the method wherein the target polynucleotide encodes a gene of clinical importance (Column 10, lines 10-18) but they do not specifically teach the probe set comprises a degenerate probe. However, Lockhart et al teach a similar probe set comprising a degenerate probe wherein the degenerate probe is useful for analyzing polynucleotides encoding polypeptide sequences of interest (Column 2, lines 22-44). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe sets of Gentalen et al by including degenerate probes for the expected benefit of analyzing clinically important polynucleotides and the encoding polypeptide sequences of interest as taught by Lockhart et al (Column 2, lines 22-44).

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7. Claims 5, 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al (U.S. Patent No. 5,541,308, issued 30 July 1996) in view of Lockhart et al (6,329,140, issued 11 December 2001).

Regarding Claim 5, Hogan et al disclose a set of probes for detecting at least one target polynucleotide (e.g. *Mycobacterium avium*) from a plurality of different targets (Column 12, lines 58-Column 13, line 35). The set of probes comprises a collection of different promiscuous probes (i.e. genus-specific probes 1-4, Example 8, lines 15-53) wherein the probes are capable of hybridizing to sequences shared by at least two target sequences (i.e. *Mycobacterium* genus) wherein a predefined combination of promiscuous probes hybridizes to at least two targets and provides specificity of detection (Tables 22-23) but they do not specifically teach the probe set comprises a degenerate probe. However, Lockhart et al teach a similar probe set comprising a degenerate probe wherein the degenerate probe is useful for analyzing polynucleotides encoding polypeptide sequences of interest (Column 2, lines 22-44). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe sets of Hogan et al by including degenerate probes for the expected benefit of analyzing clinically important polynucleotides and the encoding polypeptide sequences of interest as taught by Lockhart et al (Column 2, lines 22-44).

Regarding Claim 7-9, Hogan et al teaches the probes are immobilized (Column 28, lines 2-14) but does not teach a high density array of probes or linkage via a spacer. However, these elements are taught by Lockhart et al who teach the preferred immobilization of probe includes attaching probes to a high density array via a spacer i.e. linker (Column 22, lines 11-35) wherein their arrays are especially useful for distinguishing between mycobacterium species (Column 12, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Hogan et al by immobilizing the probes on a high-density array via a spacer as taught by Lockhart et al based on Lockhart's expressed suggestion to do so (Column 12, lines 1-5).

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Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Application No. 10/343,170. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic

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Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
June 30, 2004